



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 11 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Jeffrey Fleishman
Manager, Regulatory Affairs and Quality Assurance
Immunostics, Inc.
3505 Sunset Avenue
Ocean, NJ 07712

Re: k041728
Trade/Device Name: Immuno/ hCG Detector™- Urine
Immuno/hCG Detector Stix™
Immuno/hCG Detector Combi™
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: June 23, 2004
Received: June 25, 2004

Dear Mr. Fleishman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

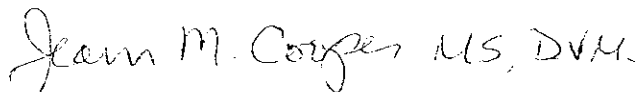
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041728

Device Name: Immuno / hCG Detector™ - Urine

Indications for Use:

The Immuno / hCG Detector™ - Urine is for the rapid and qualitative determination of Human Chorionic gonadotropin (hCG) in urine as an aid for the early detection of pregnancy. It is intended for professional and laboratory use only.


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041728

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

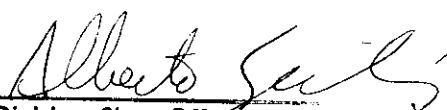
Indications for Use

510(k) Number (if known): K041728

Device Name: Immuno / hCG Detector Stix™

Indications for Use:

The Immuno / hCG Detector Stix is for the rapid and qualitative determination of Human Chorionic gonadotropin (hCG) in urine as an aid for the early detection of pregnancy. It is intended for professional and laboratory use only.


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041728

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Indications for Use

510(k) Number (if known): K041728

Device Name: Immuno / hCG Detector Combi™

Indications for Use:

The Immuno / hCG Detector Combi™ is for the rapid and qualitative determination of Human Chorionic gonadotropin (hCG) in urine or serum as an aid for the early detection of pregnancy. It is intended for professional and laboratory use only.


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041728

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)